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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,529	12/17/2001	Ann M. Lees	10797-004003	4848
26161	7590	04/07/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MITRA, RITA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/023,529

Applicant(s)

LEES ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38-84 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' preliminary amendment filed on December 17, 2001 is acknowledged. Amendment to specification has been entered. Claims 1-37 have been canceled. New claims 38-84 have been added and entered. Therefore claims 38-84 are pending.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 38-42, 53-55, 62-65, 75, 79-81, drawn to an isolated polypeptide that binds to LDL and is at least about 80%, or 90% or 95% identical to the amino acid sequence of SEQ ID NO: 5, or at least 80% or 90% or 95% identical to a portion of amino acid sequence of SEQ ID NO: 5; an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 5, wherein the polypeptide consists of the amino acid sequence of SEQ ID NO: 5; an isolated polypeptide comprising an amino sequence identical to a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 5; wherein the said polypeptide sequence binds to LDL; an isolated polypeptide comprising a polypeptide sequence, wherein the peptide sequence binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO:5. Classified in class 530, subclass 350, 300, 359; class 435, subclass 440, 441.

Should Group I be elected, applicants are required to select SEQ ID NO: 5 from claims 75, 79, 80 and 81

- II. Claims 43-47, 56-58, 67-70, 75, 79-81, drawn to an isolated polypeptide that binds to LDL and is at least about 80%, or 90% or 95% identical to the amino acid sequence of SEQ ID NO: 8 or at least about 80%, or 90% or 95% identical to a portion of amino acid sequence of SEQ ID NO: 8; an isolated polypeptide

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comprising the amino acid sequence of SEQ ID NO: 8, wherein the polypeptide consists of the amino acid sequence of SEQ ID NO: 8; an isolated polypeptide comprising a peptide sequence identical to a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 8; wherein the said polypeptide sequence binds to LDL; an isolated polypeptide comprising a polypeptide sequence, wherein the peptide sequence binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 8. Classified in class 530, subclass 350, 300, 359; class 435, subclass 440, 441.

Should Group II be elected, applicants are required to select SEQ ID NO: 8 from claims 75, 79-81.

III. Claims 48-52, 59-61, 71-74, 76, 78, 82-84, drawn to an isolated polypeptide that binds to LDL and is at least about 80%, or 90% or 95% identical to the amino acid sequence of SEQ ID NO: 44, or at least 80% or 90% or 95% identical to a portion of amino acid sequence of SEQ ID NO: 44; an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 44, wherein the polypeptide consists of the amino acid sequence of SEQ ID NO: 44; an isolated polypeptide comprising an amino sequence identical to a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 44; wherein the said polypeptide sequence binds to LDL; an isolated polypeptide comprising a peptide sequence that binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of SEQ ID NO: 44; an isolated polypeptide comprising a peptide sequence, wherein the peptide sequence binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 44. Classified in class 530, subclass 350, 300, 359; class 435, subclass 440, 441.

IV. Claim 66, drawn to an isolated polypeptide comprising a peptide sequence

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identical to a fragment of at least 10 amino acid residues of SEQ ID NO: 29.

Classified in class 530, subclass 350, 300, 359.

- V. Claim 66, drawn to an isolated polypeptide comprising a peptide sequence identical to a fragment of at least 10 amino acid residues of SEQ ID NO: 41. Classified in class 530, subclass 350, 300, 359.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III/IV/V are related as polypeptide. However, the polypeptides differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions II and III/IV/V are related as polypeptide. However, the polypeptides differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions III and IV/V are related as polypeptide. However, the polypeptides differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions IV and V are related as polypeptide. However, the polypeptides differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

The restriction requires for a selection of a single sequence of amino acid sequence because each sequence has a different chemical and physical property (See specification pages 11+). For example the rabbit LBP-3 has amino acid sequences of SEQ ID NO: 5 (Fig. 5); while human LBP-3 has amino acid sequences of SEQ ID NO: 44 (Fig. 8A). In addition the invention also includes fragments and variants, which have different amino acid sequences, which are distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Jack Brennan on March 8, 2004, to request an oral election to the above restriction requirement, but did not result in an election being made.

### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

March 30, 2004



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